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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,808	10/16/2000	Ib Mendel-Hartvig		2872

7590 08/26/2004

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1900 Chemed Center
255 East Fifth Street
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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09/582,808	10/16/2000	Mendel-Hartvig	

EXAMINER
Coutts

ART UNIT	PAPER
1641	20040824

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

In the Advisory Action mailed July 28, 2004 under No. 7 For purposes of Appeal. Examiner inadvertently forgot to check that the proposed amendment(s) will be entered. Therefore, Examiner has issued a Supplemental Advisory Action in which the box in No. 7 is checked to indicate that the propsed amendment(s) will be entered.

Supplemental **Advisory Action**	**Application No.** 09/582,808	**Applicant(s)** MENDEL-HARTVIG ET AL.	
	Examiner Gary W. Counts	**Art Unit** 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *28 June 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *42-83*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

DETAILED ACTION

Attachment to Supplemental Advisory Action

Continuation of 5 NOTE: Applicant argues that Charlton et al does not teach or suggest a method or test kit as defined in claims 42 and 63 wherein a biospecific affinity reactant (Capturer) is firmly anchored to a flow matrix via immobilized particles exhibiting hydrophilic groups on their surface, particularly in combination with an analytically detectable reactant (Reactant*) having labeled particles as an analytically detectable group. Applicant argues that the hydrophobic particles of Charlton et al absorbed very strongly to flow matrices such as nitrocellulose membranes and that the hydrophobic features of the particles promote non-specific absorption of an analytically detectable reactant (Reactant*) and/or analyte and therefore decrease the sensitivity of test methodologies. Applicant argues that Charlton does not teach or suggest immobilized particles exhibiting hydrophilic groups on their surface. This is not found persuasive because the Examiner has not relied upon Charlton et al for teaching this limitation but rather has relied upon Batz et al for teaching the advantages of hydrophilic particles in binding assays and for their advantages over hydrophobic particles used in binding assays. Furthermore, Charlton et al disclose that any ligand which has heretofore been assayed using known immunoassay procedures or known to be detectable by such procedures can be used (col 4).

Applicant argues that the deficiencies of Charlton et al are not resolved by Batz et al. Applicant argues that Batz et al does not teach or suggest a flow matrix immunoassay or use of the latex particles described therein in a flow matrix

immunoassay. This is not found persuasive because Examiner has not relied upon the Batz et al reference for this limitation but rather has relied upon Charlton et al for teaching this limitation. Applicants state that there is no teaching or suggestion by Batz et al that their latex particles are suitable for adsorbtion to a second solid support or matrix. This is not found persuasive because although Batz et al does not specifically suggest that their latex particles are suitable for adsorption to a second solid support or matrix it is within the realm of one of ordinary skill in the art to replace one solid phase particle having immobilized biospecific affinity reactant for another solid phase particle comprising a biospecific affinity reactant because the use of solid phase particles in binding assays is very well known in the art.

In response to applicants argument that Batz et al does not teach or suggest their particle will provide improved sensitivity in flow matrices and decrease the tendency of non-specific absorption in a detection zone as is obtained according to the present invention. In response to applicant's argument that Batz et al does not teach or suggest their particle will provide improved sensitivity in flow matrices and decrease the tendency of non-specific absorption in a detection zone as is obtained according to the present invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant states that in view of Batz et al's concern for impairment of reactant activity, one of ordinary skill in the art would be disinclined to absorb such particles to a

second solid support, as one of ordinary skill would presume that such adsorbtion would impair the structure and thus the activity of the biologically active proteins with which Batz et al are concerned. This is not found persuasive because this is not a concern, the Applicant has mischaracterized the Batz et al reference. Batz et al teaches that immunoligcally-active substance that are bound to the particles have not be impaired and are structurally active. With respect to the statement made by Applicant concerning the impairment of reactant activity and structure by adsorption of the particle to a second solid support, this is an assertion made by the Applicant without any support or evidence. Therefore, the combination of Charlton et al and Batz et al is maintained.

Applicant argues that Brown et al fail to teach that the particle size is smaller than the flow channels of the matrix or, as required by the present claims, that the particles have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix. This is not found persuasive because Brown et al specifically teaches that the average diameter of the particles is less than the average pore size of the matrix (abstract) and as stated in the previous office action the optimum dimension and diameter of the flow channels and particles size can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Therefore, it is the Examiner position that the combination of Brown et al with Charlton et al and Batz et al is appropriate and thus reads on the instantly recited claims.

Applicant argues that Bennich et al does not resolve the deficiencies of Charlton et al in view of Batz et al and Brown et al. Applicant argues that Bennich et al fail to teach or suggest use of a flow matrix as required by the present claims. This is not found

persuasive because Examiner has not relied upon Bennich et al for teachings this limitation but rather has relied on Charlton et al for this limitation. Applicant is reminded that applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Devlin et al does not teach or suggest a method or test kit as presently claimed or for modifying the teachings of Charlton et al to provide such a method or test kit. Particularly, applicants find not teaching or suggestion by Devlin et al for a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable reactant (Reactant*) has labeled particles as an analytically detectable group and a biospecific affinity reactant (Capturer) is anchored to the flow matrix via immobilized particles of a size and function as claimed and exhibiting hydrophilic groups on their surface. This is not found persuasive because Examiner has not relied upon Devlin et al for these limitations but rather has relied upon Charlton, Batz and Brown for these limitations. Examiner has relied upon Devlin for teaching immunoassay procedures for determining an analyte of interest. Furthermore, Charlton et al disclose that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or know to be detectable by such procedures.

Applicant argues that Dafforn, does not teach or suggest a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable group reactant has labeled particles as an analytically detectable group and a biospecific

affinity reactant is anchored to the flow matrix via immobilized particles exhibiting hydrophilic groups on their surface. This is not found persuasive because Examiner has not relied upon the tertiary reference for these limitations. The above limitations are taught by the combination of the primary and secondary references. Examiner has relied upon Dafforn for the application of reagents upstream of a sample applicant and the advantages of this type of application (see previous office action).

Applicant argues that Self broadly discloses an immunoassay using an amplified cyclic detection system and that Self does not teach or suggest the limitations as recited in claims 42 and 63 and that the combination of Charlton et al, Batz et al, Brown et al and Self does not enable one of ordinary skill in the art to conduct the presently claimed method or to make and sue the presently claimed methods and test kits obvious. This is not found persuasive because as stated in the previous office action and above Self et al show that immunoassays are used for the detection and/or determination of autoimmune diseases and that and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances. Furthermore, Charlton et al disclose that the test cell can be used to detect any ligand which has been assayed using known immunoassay procedures, or known to be detectable by such procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
July 16, 2004

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
8/24/04